December 4, 1985

R. A. Guyton, M.D.

Subject: Environmental Health/Industrial Hygiene/Toxicology
Activity Report - November, 1985

1. The presence of dioxins and related furans in our EDC tars from Calvert City and LaPorte has not been resolved. A meeting was held with Mr. Holbrook and other staff to provide further background and recommendation; however, no significant steps were accepted.

   In a subsequent meeting to discuss dioxin issues within the company, Dr. Hinderer informed Dr. O'Mara of the unsatisfactory management of the dioxin/furan concerns at Calvert City and LaPorte. He also discussed the unresolved issue of notifying workers at LaPorte of serum PCB levels. Dr. O'Mara agreed that these issues were very important and that they should be addressed and monitored by the top management. He stated that he would discuss these items with Mr. Hall.

2. Dr. Hinderer attended a toxicology symposium on butadiene which was sponsored by IISRP. Toxicologists from EPA, NIEHS, NIOSH, OHSA and Industry met to discuss current research on this chemical and to share ideas. Some of the most recent work by NIEHS and CIIT provided some insight into differences in the carcinogenic response of BD in rats and mice. NIEHS reported that higher levels of mono and diepoxide metabolites of BD were found in the mouse and indicated that future studies will look at the primate. CIIT also provided data which indicates that the high incidence of thymic lymphomas in mice may be due to the presence of retroviruses common to the species/strain studied. The results were discussed in light of the weak response in rats and the absence of any excess of cancers in the IISRP epidemiology study.

3. The Fabricated Polymers Division has developed a product which is effective in controlling the mine acid problem. Because this product exhibits biocidal activity against the microorganism that produces the acid, we have been informed of pesticide registration requirements and have assisted this group in setting up a meeting with the EPA.

4. Further discussion with USP regarding the Carbomer monographs indicates that the resolution of the total volatile impurities and residual acrylic acid issues will not hold up publication of a Carbomer family monograph. The new gas chromatographic benzene method will be published in the next Pharmacopoeial Forum for general comment. It should then be formally adopted and published in the 4th USP-NF Supplement, July, 1986. The family monograph including all Carbomers will be published in the March-April Pharmacopoeial Forum for comment and may well be able to be published in the 4th USP-NF Supplement also.

A potential Pakistani customer wants to use Carbopols 934 and 940 in some pharmaceutical applications. However, before he may import the substances it must be certified that they comply with the Pakistani food and drug laws. A review of the Pakistani laws and regulations shows that the Carbopols comply and we could so certify.

A New Zealand customer is investigating the use of Carbopol as a time release agent for veterinary drugs. In some cases the active drug would be released over a period of 200 days while inserted into the rumen of an animal. Unfortunately, we do not have data applicable to this type of application to support such use. The customer indicates this could become a sizable market.

5. Dr. Hinderer visited Southwest Research Institute to review the progress of the VI studies of HCl and PVC. Biopsies of the respiratory tract and mid-lobe removal were conducted on some of the baboons which had completed the one year post-exposure period. Furthermore, guinea pigs were exposed to 5000 ppm HCl. Although HCl produced acute respiratory effects in the baboons, no pulmonary impairment has been noted at three months. Preliminary data at six months and one year for the 5000 ppm baboons has suggested that some decrease in pulmonary function may exist; however, the histopathological evaluations have failed to reveal any significant lesions.

6. The initial panic situation over DEHP caused by the Consumer Product Safety Commission (CPSC) Chronic Hazard Advisory Panel (CHAP) report appears to have subsided somewhat. Both SPI and CMA have issued position statements on DEHP in consumer products. Both criticize the CHAP report and conclude that DEHP does not pose a serious human health hazard problem.

   At least one of our suppliers (Eastman) does not intend to label DEHP as a carcinogenic hazard based on the NTP study and subsequent OSHA Hazard Communication Regulation requirements.

7. Mr. Bachtel received notice of an appointment to an SPI task force to assess the value of a third party certification program for indirect food additives. This would be an effort to obtain an outside evaluation of the GRAS or no migration status of indirect food additives, i.e. food contact article ingredients. The need for such a program has been brought on by FDA's inability or unwillingness to react to such requests. The Flavor and Extract Manufacturers Association currently has such a program established for its members. The FDA apparently does not object to their findings.

8. Brecksville has just supplied the additional data requested by the FDA for our current Goodrite 3125 petition. A preliminary analysis indicates that it will result in an approximate increase of 0.02 ppm Goodrite 3125 in the diet. This slight increase should not have a significant effect on acceptance of the petition. The data will be submitted by BFG; if additional data is required we will need to determine whether BFG or Ciba-Geigy will submit it.

   We have supplied data to the National Sanitation Foundation on the chemical structure, migration and FDA clearance for Goodrite 3125. We have requested NSF acceptance for use of this product in polyerethane for use in potable water applications. Under our contract with Ciba-Geigy we can still make this product for internal consumption.

9. Battelle finally forwarded the "Special Report" which will produce our internal MSDS' for the various plants upon request. After many frustrating hours of trying to recompile "Report" Sherrill Snedecker was informed by Battelle that the "Special Report" was developed on a prototype Report Module instead of a production version of the Report Module. Consequently, Battelle has to replace our Report Module to accommodate the size of the "Special Report". The module is to be sent Federal Express this week. This new module should be covered under BFG's maintenance contract for Basic.

10. The Department is being inundated with MSDS' and the urgent need for a productive process flow is paramount.

11. We assisted the Carbopol Group in providing toxicological information to the P & G Detergent Group. Dr. Hinderer provided an overview of the data and discussed benzene-related health issues. Both P & G and the Carbopol Group were very pleased with our assistance.

12. We have submitted a proposal to NSF for alternative toxicological tests for the orange dyes which we wish to use in CPVC pipe for house sprinkler systems.

13. Mary Beth Butterfield met with Mary Moldea in the Medical Center regarding the Urine Cytology program for retirees and former employees. The mailing of notifications and test kits for those requesting them will now be handled by this department. All files pertaining to this aspect of the program now reside in D/0020.

14. Radiation exposure data formerly entered by Ms. Hodgson are now being entered here. All monitoring data received from the tire plants are also being reviewed prior to entry.

15. Mrs. Wallace entered 4,384 records into the system this month.

H. W. Dietz

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March 3, 1986

H. W. Dietz

Subject: Toxicology Activity Report - February, 1986

1. I assisted the FPD in preparing a preliminary information package for submittal to EPA. Following this activity we met with EPA to determine the requirements for pesticide registration of four Promac products. The FPD has asked that every effort be made to expedite testing. As a result I have requested the necessary protocols which will be hand delivered to me next week at the SOT annual meeting.

2. I have been working with the CMA Rubber Additives Panel in developing comments on the proposed test rule for MBT. These comments were submitted to EPA on February 28.

3. We have been notified that EPA is preparing a CHIP (Chemical Hazard Information Profile) on Cure-rite 18. With the assistance of the SP&C business group I have assembled a detailed package covering physical chemical properties, workplace and consumer exposure, environmental fate, and human and environmental effects. This is a very important project because of the attention rubber chemicals are receiving by EPA (i.e. test rules). Fortuitously, we have developed a considerable amount of data.

   In the future I plan to review information deficiencies with the product group. Hopefully if we can complete the development of a minimal database, we will be able to avoid an expensive test rule on CR-18.

4. The Estane business group is continuing to pursue potable water pipe clearances through a joint project with Shell and Insitu Form. Earlier this month we met with representatives of Shell and the N.Y. State Dept. of Health and I reviewed the limited toxicological data on Estane polyethers with them. No estimate was given as to when we might have a response. However, Shell is taking the lead role and will keep us informed.

5. I continue to be involved with the Pappion lung cancer case and am now completing my review of the background information. My deposition and the trial is scheduled for March.

6. The New Products Group is working with Velsicol in evaluating some chemicals as plant growth regulators. I have provided guidance regarding TOSCA and FIFRA test requirements.

7. I met with the SP&C Group to assist them in prioritizing research to find alternatives to benzene as a solvent for Carbopol. Additional toxicity information review was requested on several solvents.

8. OSHA has begun preliminary maneuvering to regulate BD. I am working with IISRP in preparing comments. We believe that the present ACGIH TLV of 10 ppm is adequate and that OSHA does not have any scientific basis to set a standard of 1 ppm.

9. The VI Technical Committee met this month and I provided an update on the baboon and rodent studies on HCl. All work is proceeding satisfactorily. The medical/toxicological subcommittee has also been asked to review the basis for the EPA dioxin risk assessment; an FOI request has been submitted to EPA.

10. Dr. Hinderer has prepared a draft submission for compliance with the TOSCA 8d health and safety reporting rule for vinyl acetate. This draft has been submitted to the Geon Company for their review.

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R. K. Hinderer

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